K002514

MAY 31 2001

510 (k) Summary

Product Name

Caduceus Health Care Ltd. - CadHealth System CHP-001

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Caduceus Health Care Ltd.
CIBC Building, Suite 708
Halifax, Nova Scotia
B3J 3K8

Contact Person:

Barry Martin
President and CEO
Caduceus Health Care Ltd.
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barrym@caduceus-healthcare.com

Date Prepared: July 20, 2000

Device Name:

Classification Name:	Personnel Telemedicine Device
Trade Name:	CadHealth Telehealth System
Classification:	Type II

Predicate Devices:

1	American TeleCare Personal Telemedicine System -	K952882
2	Eastman Kodak Home Monitoring System -	K983928
3	American Telecare Aviva System – SL1010 -	K003550
4	American Telecare Aviva System – 1010, 2020 -	K981533

5	American Telecare Digital Personal Telemedicine -	K973873
6	Cybercare EHC 200	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2001

Mr. Kirk Nielsen
Vice President, IT
Caduceus Health Care Limited
CIBC Building, Suite 708
1809 Barrington Street
Halifax, Nova Scotia
Canada B3J 3K8

Re: K002514
Trade Name: CadHealth System, Model CHP-001
Regulation Number: 870.2910
Regulatory Class: II (two)
Product Code: DRG
Dated: March 7, 2001
Received: March 9, 2001

Dear Mr. Nielsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002514

Device Name: CadHealth CHP-001

Indications For Use:

The CadHealth CHP-001 system is intended for use as a monitoring system, which provides remote vital signs monitoring of patients and the ability to listen to patient's heart and lung sounds. The CadHealth System monitors blood pressure, pulse, oxygen saturation, prothrombin time, and glucose readings.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002514

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)